NDA 20-491/S-003

Pharmacia & Upjohn Company
Attention: Ms. Rebecca K. Tong, M.S.
7000 Portage Road
Kalamazoo, MI 49001-0199

20 APR 2001

Dear Ms. Tong:

Please refer to your supplemental new drug application dated August 26, 1998 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Corvert (ibutilide fumarate) Injection, 0.1 mg/ml.

We acknowledge receipt of your submission dated November 15, 2000 that constitutes a complete response to our September 26, 2000 approvable letter.

This supplemental new drug application provides for final printed labeling revised under the **PRECAUTIONS/Geriatric Use** subsection in accordance with 21 CFR 201.57(f)(10).

We note that minor editorial changes were made under the **CLINICAL PHARMACOLOGY/Clinical Studies**, **PRECAUTIONS/Geriatric Use**, and **Use in Patients With Hepatic or Renal Dysfunction** subsections.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your submission of November 15, 2000). Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Quynh Nguyen, Pharm.D.
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research